REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 10-74 are now pending, and claims 29-74 are withdrawn. In addition, the Office Action states that claims 23 and 27-28 are not being examined because they include non-elected species.

I. Election/Restriction

The Office Action makes the restriction requirement final and notes Applicants' election with traverse of Group I, claims 10-28. The Office Action states that claims 23 and 27-28 are not being examined, because they include non-elected species.

A. Summary of the Elected Species

In the Restriction Requirement dated August 11, 2005, the Examiner made three species election requirements: (1) aqueous dispersions or dry compositions (claims 20 and 23); (2) a single surface modifier among those listed in claims 25-28 and 63-66; and (3) a single polymeric resin among those listed in claims 45-48.

In response, Applicants elected aqueous dispersions (recited in claim 20), a non-ionic surface modifier which is polyvinylpyrrolidone as the surface modifier (recited in claims 25 and 26), and cross-linked polystyrene as the polymeric resin. Claims 23, 27, and 28 recite non-elected species.

B. Applicants are not Required to Amend the Claims to only Recite the Elected Species

As noted in Applicants' Response to the Restriction Requirement, a species election requirement is imposed for ease of examination. However, once the Examiner finds the elected combination of species allowable, the search must be extended to the other recited species. Thus,

if the elected species are found allowable, the Examiner must extend the search to encompass the species recited in claims 23, 27 and 28.

II. Claim Rejections – 35 U.S.C. § 103

Claims 10-22 and 24-26 stand rejected under 35 U.S.C. § 103 as allegedly obvious over U.S. Patent No. 5,145,684 to Liversidge *et al.* ("Liversidge") in view of Lacy *et al.*, DRUG INFORMATION HANDBOOK, pp. 95-96 (Lexi-Comp, Inc. 1993) ("DIH"). The Office Action states that Liversidge teaches each and every element of the claims, except beclomethasone dipropionate. DIH is cited to remedy this deficiency. According to the Office Action,

> It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general formulations of Liversidge on formulations containing active agents including corticosteroids, to have looked in the art for other specific species of corticosteroids suitable for formation of compositions, as disclosed in Drug Information Handbook, with reasonable expectations of successfully preparing formulations comprising different active agents for treating different disorders.

Applicants respectfully traverse this ground of rejection.

The prior art does not teach or suggest a nanoparticulate composition of beclomethasone dipropionate, as claimed, nor does the prior art provide a reasonable expectation of success in obtaining the claimed invention upon combining the teachings of the cited references. Liversidge generally relates to nanoparticles of a crystalline drug substance with a surface modifier absorbed on the surface thereof. In that regard, Liversidge discloses a lengthy list of classes of drugs substances, such as corticosteroids, and examples of some particular drug substances, such as Steroid A. However, Liversidge makes no mention of beclomethasone dipropionate.

DIH does not remedy the deficiencies of Liversidge because there is no motivation to combine the references. Specifically, there is no motivation for a skilled artisan to select beclomethasone dipropionate from the large numbers of drugs falling into the categories listed in

Liversidge. Indeed, Liversidge makes no mention of aerosol formulations, which is the form in which beclomethasone dipropionate is administered. DIH, p. 95. In addition, Liversidge teaches that "not every combination of surface modifier and drug substance provides the desired results [of a stable nanoparticulate composition]." Liversidge, col. 7, lines 21-23. Thus, one of skill in the art would have had no expectation of success in selecting beclomethasone dipropionate and employing the teachings of Liversidge. *See* MPEP § 2143.02. Accordingly, Liversidge and DIH fail to render the claimed invention obvious.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

III. Obviousness-Type Double Patenting

A. U.S. Patent No. 6,264,922

Claims 10-22 and 24-26 stand rejected "under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-16 of U.S. Patent No. 6,264,922 B1." Office Action at 5. According to the Office Action, the claims "are not patentably distinct from each other because the examined claims are anticipated by the reference claims." *Id.* Applicants respectfully traverse this ground of rejection.

While Applicants respectfully disagree with the Examiner's assertion, filed herewith for the sole purpose of advancing the prosecution of this case is a Terminal Disclaimer for U.S. Patent No. 6,264,922.

B. U.S. Patent No. 6,811,767

Claims 10-22 and 24-26 stand "rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-13 of U.S. Patent No. 6,811,767 B1." Office Action at 5. According to the Office Action, the claims "are

not patentably distinct from each other because the examined claims are anticipated by the reference claims." *Id.* Applicants respectfully traverse this ground of rejection.

An obviousness-type double patenting rejection is inappropriate because the claimed invention is not rendered obvious in view of claims 1-13 of the '767 patent. Indeed, claims 1-13 of the '767 patent recite "naproxen, triamcinolone acetonide, budesonide, and an anti-emetic." There is no teaching or suggestion in the claims of employing beclomethasone dipropionate, as claimed. MPEP § 804(III) ("[A] double patenting rejection must rely on a comparison with the claims in an issued or to be issued patent"). Moreover, "[d]omination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection." MPEP § 804(II). Thus, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

C. U.S. Patent No. 5,747,001

Claims 10-22 and 24-26 stand "rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,747,001." Office Action at 6. According to the Office Action, the claims "are not patentably distinct from each other because the examined claims are anticipated by the reference claims." *Id.*

While Applicants respectfully disagree with the Examiner's assertion, filed herewith for the sole purpose of advancing the prosecution of this case is a Terminal Disclaimer for U.S. Patent No. 5,747,001.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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